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10/695,471	10/28/2003	Janaswamy Madhusudana Rao	0640/71348/JPW/AG	5608

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EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/695,471

Applicant(s)

RAO ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
4a) Of the above claim(s) 13-52 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-12 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT, Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-12, and the species *Cyclea pelate*, in the reply filed on April 25, 2005 is acknowledged. The traversal is on the grounds that the inventions of the cited groups are not independent and that it would not be a serious burden for the examiner to examine each of the instantly claimed inventions. This is not found persuasive for the reasons set forth clearly in the previous Office action.

The inventions of Groups I-V are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

The requirement is still deemed proper and is therefore made **FINAL**.

The claims have been examined, insofar, as they read on the elected invention.

Claims 1-3 and 7 are under examination, as they read on the elected invention. However, as set forth in the rejection made under 35 U.S.C. 112, second paragraph set forth below, a thorough search of the term *Cyclea pelate* in both patent and non-patent literature did not result in any references referring to the term. Therefore, the search

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was extended to include other "optional" ingredients recited in the Markush group of Claim 1.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, Applicant should avoid the use of the phrase "The present invention", which appears in line 1 of the abstract.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 1, is rendered vague and indefinite by the phrase "synergistical herbal composition" because it is unclear as to what amount (e.g., amount range, proportion, and/or ratio) of each claimed ingredient actually define a synergistic amount with respect to the other ingredients so as to provide a combined synergistically effective amount of the overall composition. Accordingly, the metes and bounds of this phrase (e.g., the synergistically effective amounts of each ingredient with respect to the others) are not clearly nor adequately delineated with respect to the synergistic amounts of the individual components. Please note that synergism is an unpredictable phenomenon which is highly dependent upon specific proportions and/or amounts of particular ingredients. Accordingly, the recitations of the amounts ranges and/or proportions (e.g., ratios) of each claimed ingredient necessary to provide a synergistic combination is deemed essential (see, e.g., MPEP 2172.01) and, thus, should be defined in the independent claim language itself.

The metes and bounds of Claim 1, lines 1 to 2, are rendered vague and indefinite by the phrase, "said composition essentially comprising", because it is unclear as to what subject matter encompasses the meaning of the phrase "essentially comprising".

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For instance, does Applicant intend to direct the subject matter of the claimed invention to a composition comprising one or two or three or more ingredients other than those ingredients recited in the claim language of Claim 1? Or, can the instantly claimed invention only consist essentially of the claim-designated ingredients? The lack of clarity renders the claim ambiguous, especially since the instantly claimed composition may "optionally" comprise additional ingredients.

Claims 1-3, 7, 9 and 10 recite the terms: "*Asperagus racemosus*", "*Seaamum indicum*", "*Trachyaparmum roxburghicinum*", "*Evolvulus aidinodes*", and "*Cyclea peltate*". However, a thorough search of both patent and non-patent literature found no evidence that any of the claim-designated plants occur in nature. Thus, the claims are unsearchable as no genus-species with the prescribed names were found searchable. It appears that the terms are misspellings of *Asparagus*, *Sesamum*, *Trachyspermum roxburghianum*, *alsinoides* and *peleta*. Appropriate correction is required, if the assumption is true. If not, the Examiner's preliminary analysis and search demonstrates that the claimed subject matter cannot be adequately searched by class or keyword among patents and typical sources of non-patent literature.

The metes and bounds of Claim 8 are rendered vague and indefinite by the phrase "wherein the plant part of is *Aloe barbadensis* elio" because is it uncertain as to what is an "elio". Thus, it is unclear as to the subject matter Applicant intends to direct the instantly claimed invention since a thorough search of both patent and non-patent literature did not find any definition or reference to a plant part termed "elio".

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Objections

There are apparent misspellings throughout the claims. Applicant may overcome the objection by replacing "Asperagus" with Asperagus; "Seaamum" with Sesamum; and, "peltate" with peleta.

There is apparent omission of a comma between the terms "*Coriandum sativum*" and "*Ferula asafoetida*" in Claim 1, line 5. Applicant may overcome the rejection by placing a comma between the terms to place the claim in proper grammatical form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-7 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goel et al. (U), Goet al. (X), Hong-Yue (A*), Dehpour et al. (V), Yoshida et al. (N), Johnson (W), Blitz et al. (U1) and Khrenova et al. (V).

As discussed above in the rejection made under 35 U.S.C. 112, second paragraph, Applicant's claims are indefinite to the point where a proper search among

patent and non-patent literature is almost precluded. However, a search was conducted for what reasonably appears to be Applicant's claimed invention.

Applicant claims a synergistic herbal composition for the treatment of gastric ulcer, said composition essentially comprising powdered plant parts of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyparum roxburghicinum* and optionally, powdered plant parts of *Cyclea peleta*, *Embelea ribes*, *Coriandum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes* along with one or more pharmaceutically acceptable additives/carriers.

Firstly, on pages 105 and 106, under "*Asparagus racemosus* (Hindu-Satavari)", Goel (U) teaches compositions comprising extracts of *Asparagus racemosus* having anti-ulcer activity. Secondly, Hong-Yue teaches an antipeptic ulcer comprising powdered liquorice and clove and; and, Dehpour teaches a composition comprising powdered parts *Glycyrrhiza glabra* that is used to coat ibuprofen, which is used to treat gastric lesions. Thirdly, Yoshida teaches a composition comprising a powdered extract of *Sesamum indicum* that is beneficial in the treatment for peptic ulcers. Fourthly, on pages 101-105, under "*Musa sapientum* var. *paradisiaca*", Goel (U) further teaches the anti-ulcerogenic effects of compositions comprising dried powder of *Musa sapientum*. Also see further teachings of Goel (X). Fifthly, Johnson teaches a *Trachyparum roxburghicinum* as having functional effect in the treatment of dyspepsia. Finally, Khrenova teaches that the fruits of *Coriandum sativum* are useful in the making of antiulcerous drugs.

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The teachings of Goel, Hong-Yue, Dehpour, Yoshida, Johnson and Khrenova are set forth above. The prior art does not teach a composition comprising each of the instantly claimed ingredients. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art; and one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the claim-designated ingredients in the making of the instantly claimed composition because at the time the invention was made each of the powdered plant parts of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyparmum roxburghicinum*, as well as the fruits of *Coriandum sativum*, were known in the art of herbal medicine to exert the functional beneficial effect for treating gastric ulcer, as evidenced by the aforementioned teachings of the prior art.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention may be predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the

components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him or her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1654

MCF
July 22, 2005